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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------|------------------|
| 09/754,106 | 01/03/2001 | Graeme I. Bell | ARCD:272USC1 | 6381 |
| 7590 | 07/01/2004 | | EXAMINER | |
| David L. Parker FULBRIGHT & JAWORSKI L.L.P. 600 Congress Avenue, Suite 2400 Austin, TX 78701 | | | SITTON, JEHANNE SOUAYA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1634 | |

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,106

Applicant(s)

BELL ET AL.

Examiner

Jehanne Souaya Sitton

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/3/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,18-40 and 63-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 16,18-40 and 63-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 16, 18, 21-23, and, drawn to methods of regulating diabetes in an animal by analyzing HNF1a and providing HNF1a to the animal, classified in class 514, subclass 2.
 - II. Claims 16, 19, 21-22, 24, and 30, drawn to methods of regulating diabetes in an animal by analyzing HNF4a and providing HNF4a to the animal, classified in class 514, subclass 2.
 - III. Claims 16, 21-22, 25 and 30, drawn to methods of regulating diabetes in an animal by analyzing HNF1b and providing HNF1b to the animal, classified in class 514, subclass 2.
 - IV. Claims 16, 26-29, 63, 66, 67, and 70-83, drawn to methods of regulating diabetes in an animal by analyzing HNF1a and inducing expression of HNF1a using HNF1a nucleic acid, classified in class 514, subclass 44.
 - V. Claims 16, 26-29, 64, 66, 69, and 70-83, drawn to methods of regulating diabetes in an animal by analyzing HNF4a and inducing expression of HNF4a using HNF4a nucleic acid, classified in class 514, subclass 44.

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- VI. Claims 16, 26-29, 65, 66, 68, and 70-83, drawn to methods of regulating diabetes in an animal by analyzing HNF1b and inducing expression of HNF1b using HNF1b nucleic acid, classified in class 514, subclass 44.
 - VII. Claims 16, 31, 32, and 91-94, drawn to methods of regulating diabetes in an animal by analyzing HNF1a and modulating HNF1a function by providing a modulator which is an agonist of HNF1a, classified in class 514, subclass 2.
 - VIII. Claims 16, 31, 35, and 91-96, drawn to methods of regulating diabetes in an animal by analyzing HNF4a and modulating HNF4a function by providing a modulator which is an agonist of HNF4a, classified in class 514, subclass 2.
 - IX. Claims 16, 31, 38, and 91-94, drawn to methods of regulating diabetes in an animal by analyzing HNF1b and modulating HNF1b function by providing a modulator which is an agonist of HNF1b, classified in class 514, subclass 2.
 - X. Claims 16, 31, 33, 34, 84, and 86, drawn to methods of regulating diabetes in an animal by analyzing HNF1a and modulating HNF1a function by providing a modulator which is an antisense molecule, classified in class 536, subclass 24.5.
 - XI. Claims 16, 31, 36, 37, 87, and 88, drawn to methods of regulating diabetes in an animal by analyzing HNF4a and modulating HNF4a function by providing a modulator which is an antisense molecule, classified in class 536, subclass 24.5.
 - XII. Claims 16, 31, 39, 40, 89, and 90, drawn to methods of regulating diabetes in an animal by analyzing HNF1b and modulating HNF1b function by providing a modulator which is an antisense molecule, classified in class 536, subclass 24.5.
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XIII. Claims 16, 31, 36 and 97, drawn to methods of regulating diabetes in an animal by analyzing HNF and modulating HNF function by providing a modulator which is a transcriptional modulator, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, and IV, and VII, and X and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions have different modes of operation and different functions.

3. Inventions II, and V, and VIII, and XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions have different modes of operation and different functions.

4. Inventions III, and VI, and IX, and XI and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions have different modes of operation and different functions.

5. Groups I-III, IV-VI, VII-IX, and X-XII are each drawn to methods requiring different reagents, reaction parameters and reaction conditions. Each of groups I-III for example, are drawn to modulating, or altering the expression of or administering a different HNF molecule.

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These molecules, HNF1a, HNF4a, and HNF1b are structurally and functionally different proteins, encoded by structurally and functionally different nucleic acids, and thus patentably distinct from each other. As such, methods of making, altering, or using these proteins and nucleic acids are patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for each group is not required for each additional, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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11. Additionally, it should be noted that on page 16 of the preliminary amendment, a 2nd claim 84 exists. This claim was not placed in a specific group because it was unclear if the 2nd iteration of claim 84 was in error.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

6/28/04